MAY 2 5 2000

K001373

BIO-RAD

Bio-Rad
Laboratories

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

510(k) Summary

Submitter
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA
(949)598-1285
Fax (949)598-1555

Contact Person
Elizabeth Platt

Date of Summary Preparation
April 27, 2000

Device (Trade & Common Name)
Liquichek Immunoassay Plus Control

Classification Name
Class 1, 75JJY
CFR 862.1660: Multi-Analyte Control, All Kinds (Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed
Liquichek Immunoassay Plus Control
Bio-Rad Laboratories
Irvine, California
K961941

Statement of Intended Use
Liquichek Immunoassy Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

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Description of the Device

Liquichek Immunoassay Plus Control is prepared from human serum with added constituents of human origin, pure chemicals and therapeutic drugs and preservatives. This product is provided in liquid form for convenience

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek Spinal Fluid Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Liquichek Immunoassay Plus Control (New Device)	Bio-Rad Liquichek Immunoasay Plus Control (Substantially Equivalent Device)
Intended Use	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum.	Human serum.
Storage	-20°C	-20°C
Open Vial Claim	14 days when stored tightly capped at 2-8°C, with the exceptions of: Folate which is stable for 7 days.	14 days when stored tightly capped at 2-8°C, with the exceptions of: Insulin, PSA and Free PSA which are stable for 3 days and Folate which is stable for 7 days.
Thawed and Unopened	30 days when thawed and stored unopened at 2-8°C, with the exceptions of: Folate which is stable for 7 days, Free PSA, PSA and Prolactin which are stable for 14 days **(date of thaw should be noted).**	30 days when thawed and stored unopened at 2-8°C, with the exceptions of: Insulin and PSA which are stable for 3 days, Folate and Free PSA which are stable for 7 days and hGH and Prolactin which are stable for for 14 days **(date of thaw should be noted).**

Analytes	Similar analytes as the substantial equivalence with the following added: Iron, PTH-MM, SHBG, and Total Estrogens.	Refer to the substantially equivalent product insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 5 2000

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories
Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K001373
Trade Name: Liquichek Immunoassay Plus Control
Regulatory Class: I
Product Code: JJY
Dated: April 27, 2000
Received: May 1, 2000

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K001373

Device Name: Liquichek Immunoassay Plus Control

Indications for Use:

Liquichek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001373

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation)

Prescription Use ✓ OR Over-The Counter Use _____